K032976

APR 16 2004

510(k) Summary of Safety and Effectiveness

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter's Name:	BioValve Technologies, Inc.
Submitter's Address:	One Innovation Drive, 3 Biotech, Worcester, MA 01605
Telephone Number:	(508) 421-9500 X222
Fax Number:	(508) 421-4848
Contact Person:	Scott Huie
Date:	September 19,2003
Proprietary Name;	Mini-Ject Needlefree Injection System
Common Name:	Needle-free fluid injector
Classification Name:	21CFR 880.5430, non-electrically powered fluid injector, product code KZE
Classification:	Class II
Predicate Device:	Bioject, Biojector 2000, K960373 and K920631

Device Description: The Mini-Ject is a sterile, single use medical device. The Mini-Ject delivers 0.5ml subcutaneously. The device consists of an injector and a luer adapter to provide a means of filling the device using a standard slip lock syringe. The device is powered by a proprietary charge system wholly contained in the distal portion of the device.

Substantial Equivalence: The information provided in this premarket notification demonstrates that the proposed device is substantially equivalent to legally marketed devices. The proposed Mini-Ject device is substantially equivalent to the Bioject, Biojector 2000 (K960373 and K920631). Both devices have the same intended use to deliver medicinal to the subcutaneous tissue and both arc self-filled.

A comparison of features and principles of operation between the proposed device and predicate device is provided in the table below.

COMPARISON DATA

Feature	Predicate Device (Biojector 2000) K960373, K920631	Proposed Device: Mini-Ject Needlefree Injection System
Intended Use	Needlefrec subcutaneous and intramuscular injection system	Needlefree subcutaneous injection system
System Configuration	Three Part System - Reusable Handle - Disposable injector head - Vial Fill Adapter	Three Part System - Disposable Injector - Syringe Fill Adapter - Syringe with needle (not supplied)
Materials – Fluid Contact	Polycarbonate, Silicone, Polystyrene	Polycarbonate, Silicone. ABS, UHMWPE
Packaging	Tyvek/Film Pouch	Same
Sterility	Ethylene Oxide (ETO) Sterilized	Same
Shelf Life	3 years	3 years
Fill Adapter Provided	Yes	Yes

Summary of differences between predicate and proposed device: The predicate uses a disposable injector head and reusable handle with compressed gas source. This allows use of multiple orifices for achieving subcutaneous or intramuscular injections in various injection volumes.

The Mini-Ject has a set orifice size and energy source designed to achieve 0.5 ml subcutaneous injections only and is fully disposable.

Intended Use: The Mini-Ject is intended to be used to deliver medications approved for subcutaneous injection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 6 2004

Mr. Scott Huie
Vice President, Operations
BioValve Technologies, Incorporated
One Innovation Drive
3 Biotech
Worcester, Massachusetts 01605

Re: K032976
Trade/Device Name: BioValve Mini-Ject, Needle-Free Injection System, 0.5 ml Self-fill, Model FG-01-001
Regulation Number: 21 CFR 880.5430
Regulation Name: Nonelectrically Powered Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: January 21, 2004
Received: January 27,2004

Dear Mr. I-hie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use Statement

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510(k) Number (if known): K032976

Device Name: BioValve MiniJect Device

Indications for Use:

The Mini-Ject device is a needle-free injection system designed to deliver fluid subcutaneously. This n electrically powered device is intended lo deliver an injection of fluid by means of a high velocity jet o fluid that penetrates the skin and delivers the fluid to the subcutaneous area of the body. The MiniJect device is intended for home and professional use. It may be used by physicians, nurses and other practitioners who routinely administer injections and by patients authorized by their physicians to self inject at home.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nick Hubbard for Anthony Watson 1/8C-GHDB

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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